FDA Summary

IntraCoil® Self-Expanding Peripheral Stent

P000033

Introduction

- Non-clinical Performance
- Clinical Summary
- Panel Questions

Non-clinical Performance

- *In Vitro* **Testing**
- **Biocompatibility Testing**
- *In Vivo* **(Animal) Testing**

Clinical Summary

Clinical Summary

- **Randomized Trial Stent versus PTA**
  - **Superiority Hypothesis**
    - **25% decrease in restenosis with the IntraCoil Stent**
  - **500 patient Sample Size**

Clinical Summary

- **Primary Endpoint**
  - **9 month Restenosis (> 50% restenosis)**
  - **9 month MACE (death, Q-wave MI, target lesion revascularization) rate**

Clinical Summary

- Patient enrollment slow
- Study stopped early
- Majority of lesions treated ≤ 3cm
- Superiority hypothesis not demonstrated
- No significant safety concerns

Clinical Summary

- **Subgroup of IntraCoil patients selected based on following criteria prior to stenting:**
  - **residual stenosis ≥ 50%**

    or
  - **Grade C or greater dissection**

Clinical Summary

- **Pre-dilatation vs PTA**
  - **Fewer dilatations**
  - **Shorter dilatations**
  - **Lower dilatation pressure**

Clinical Summary

- Compared to PTA control group
  - no differences in
    - adverse event rate
    - effectiveness

Clinical Summary

- Indications for use changed
  - from:

    primary stenting for occlusive disease
  - to:

    stenting for patients meeting the subgroup criteria

Clinical Summary

- **Study Limitations:**
  - **Retrospectively selected test group**
  - **Relatively small sample size**
  - **Differences in dilatation technique**

Panel Questions

Panel Question 1

1a. Please discuss the use of the suboptimal pre-dilatation classification as a surrogate for suboptimal results with PTA.

Panel Question 1 (cont.)

1b. Please discuss any expected differences in terms of clinical outcomes between patients with suboptimal pre-dilatation and patients with suboptimal results from PTA.

Panel Question 1 (cont.)

1c. Please discuss whether there is adequate data for a primary stent indication.

If not, what additional information would be necessary to support a primary stent indication in the femoral and/or popliteal arteries.

Panel Question 2

2. Please discuss whether the clinical data are adequate to determine the safety and effectiveness of the IntraCoil Stent in the popliteal artery.

Panel Question 3

Product Labeling

3a. Please Comment on the INDICATIONS FOR USE section as to whether it identifies the appropriate patient population for treatment with this device.

Panel Question 3 (cont.)

Product Labeling

- **3b. Please comment on the CONTRAINDICATIONS section as to whether there are conditions under which the device should not be used because the risk clearly outweighs any possible benefit.**

Panel Question 3 (cont.)

Product Labeling

3c. Please comment on the WARNINGS/PRECAUTIONS section as to whether it identifies all potential hazards regarding device use.

Panel Question 3 (cont.)

Product Labeling

- **3d. Please comment on the OPERATOR'S INSTRUCTIONS as to whether it adequately describes how the device should be used to maximize benefits and minimize adverse events.**
- **3e. Do you have any other recommendations regarding the labeling of this device?**

Panel Question 4

4. Please identify and discuss the items that you believe should be contained in a physician's training program for this device.